Feedback on Protocol Authoring:

1. –On-study/Pre-study Workup
   -lab/tests/ H&IP/ etc.
   -Protocol-CRF's
   -lab, PE, tests, evaluation
   -AE's
   -End of Study
   -Response/ Outcomes

2. –Where are you planning on including forms development?

3. –Protocol Approval
   -Process
   -IRB correspondence
   -HIPAA
   -where it is in the process

3. –Companion/ Ancillary studies
   -correlative/lab science
   -QOL
   -Imaging
   -Registry
   -Other types of Protocols

4. -Administrative Information re: Regulatory data
   -Assurance numbers/ IRB information

5. –Protocol Administration
   -to include authoring but more such as registration, status, and tracking

6. –Administration data re: Process management for protocol review

7. –Focus on the flow of a protocol life cycle and how people in the system use them and develop to identify gaps and problems. These can be prioritized.

8. –Process Management
   -Workflow
   -Task Management
   -Resource Planning Allocation
   Kevin, University of Michigan

9. –Protocol Delivery Plan and Materials
   -how the protocol will be implemented in the clinic

10. –Study calendar an integral part of CTMS. Should be a primary activity that SIGs can attach functionality specific for a SIG
    David F.

11. –the structured protocol representation SIG is going to handle a schedule?
    Jon

12. –Protocol Schema
    -Calendar of events

13. –Amendments
    -Protocol life tracking
    -Event tracking
    -Web based consents/HIPPA documents current version
    Donna Mott

14. –Clinical Date management
    - need to add scheduling/protocol reminders
    - need to add clinical decision support and delete billing